

You Should Do This. No, Wait! You
Shouldn't Do This. (Less is More)
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Objectives

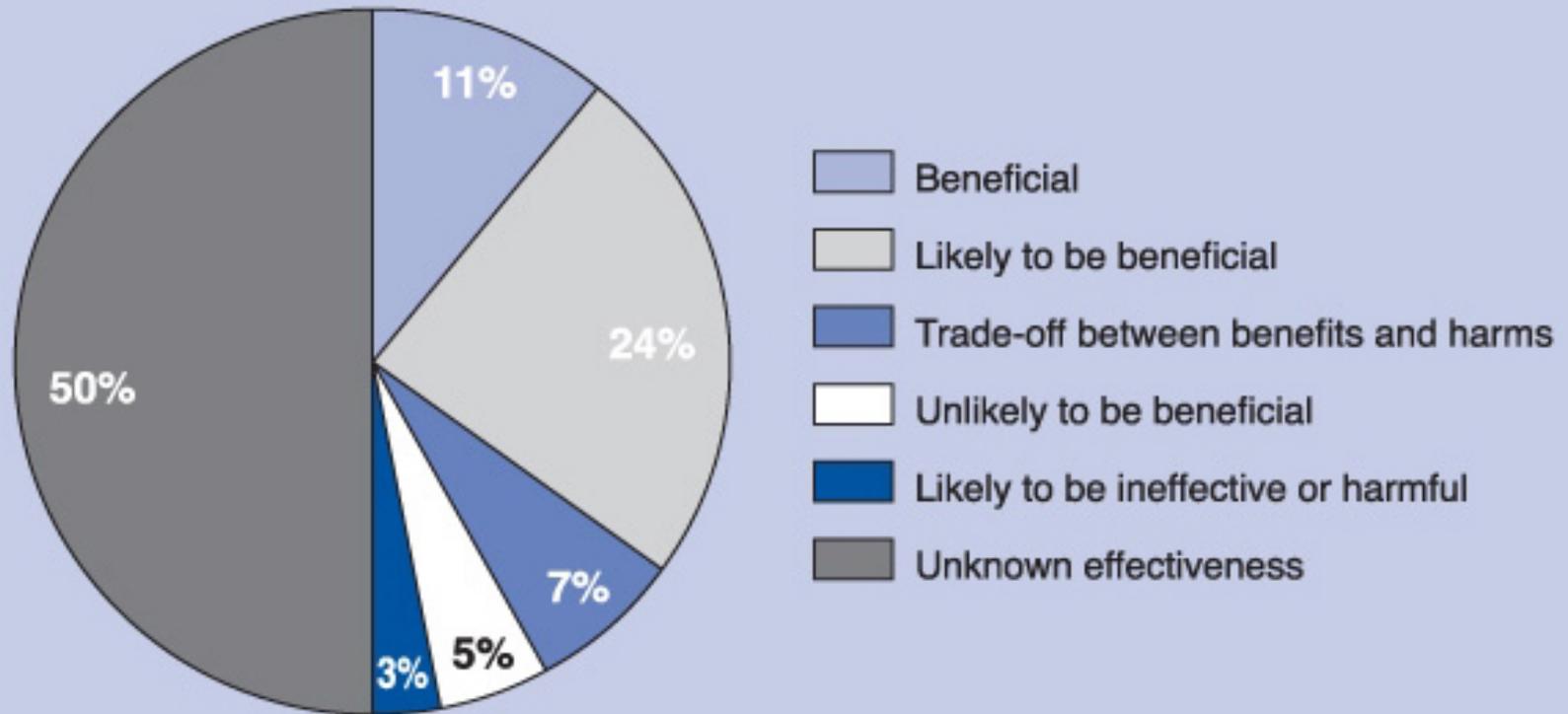
- ❑ Discuss treatments and medications which are no longer recommended
- ❑ Discuss why it is that medical recommendations change
- ❑ Discuss current treatments which may be reversed in the future



Outline

- Tests
- Surgical interventions
- Medications
- Common themes
 - Why discredited Tx continues
- Risk factors for reversal
- Possible future reversals

BMJ – Clinical Evidence



Effectiveness of 3000 treatments as reported in randomised controlled trials selected by Clinical Evidence. This does **not** indicate how often treatments are used in healthcare settings or their effectiveness in individual patients.

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- “Providing excessive health care service is more likely to occur in situations in which there is not strong evidence to document the benefits and harms of the service.”

Sirovich B, Gallagher PM, Wennberg DE, Fisher ES. Discretionary decision making by primary care physicians and the cost of U.S. health care. *Health Aff.* 2008; 27(9):813-823.



Why Unnecessary Care Continues

- ❑ Drs. Are paid to do something (fee-for-service)
- ❑ Quicker (or easier) to write a prescription
- ❑ Defensive medicine (fear of being sued)
- ❑ Patients equate testing and treatment with better care
- ❑ The “glamour of technology”



"The desire to take medicine is perhaps the greatest feature which distinguishes man from animals.

Sir William Osler

“Technology Creep”

- Technology developed for a serious condition
 - Low frequency (low prevalence)
 - High risk situation
 - Risky intervention
- With practice, technology becomes safer
- Now is applied to less risky (and much more common) situations

PCSK9 Inhibitors

- ❑ Alirocumab (Praluent) and evolocumab (Repatha) – new antibodies used to treat high cholesterol
- ❑ Touted to lower LDL by “over 60%”
- ❑ Injections, expensive (\$14,000/yr)
- ❑ “Recommended” for familial hypercholesterolemia (high cholesterol from birth), who have failed traditional treatment
- ❑ Outcomes
 - No difference in heart attacks
 - No difference in deaths
 - Very small reduction in need for repeat bypass graft
 - Doubling (but small) risk of cognitive problems

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- HRT
 - Asymptomatic bacteremia
 - Antidepressants for mild depression
 - Arthroscopic debridement of OA knee
 - Coronary stents for stable coronary artery disease
 - MRI in uncomplicated acute back pain
 - Tonsilectomy
 - Routine hernia repair in older men
 - PSA testing

HRT and WHI*

- “Logic” of hormone replacement
 - Postmenopausal – rise in heart disease, dementia, osteoporosis
 - Must be due to lack of estrogen
- Large, non-pharmaceutical funded trial (27,000)
 - Looked at both estrogen alone and estrogen-progesterone
- Outcomes
 - Increased risk of coronary heart disease, stroke, deep venous thrombosis, breast cancer, uterine cancer (estrogen alone), dementia, gallbladder disease,
 - Reduced risk of osteoporosis fractures, type 2 diabetes, all cause mortality
- HRT decreased from 22% in 1999 to 4.7% in 2010

Bacteria in the Urine

- “Asymptomatic” – no symptoms, often found when a “routine” urinalysis is ordered
- Much more common in older women (20% in those over 80)
- Was usually treated with antibiotics (for up to 10 days)
- Treatment resulted in
 - No decrease in outright infections
 - Increased adverse effects
 - Increased bacterial resistance
- Lesson – don’t do routine urine screens
 - Not necessary before surgery
 - Especially in catheterized patients

Antidepressants for Mild Depression

- Depressed but not functioning and not suicidal
- Meta-analysis of 6 RCTs treated 6-12 weeks
 - Responses
 - Placebo – 38%
 - Drugs – 41%
- Lesson – exercise, cognitive-behavioral therapy, waiting best

Arthroscopic Debridement of OA Knee

- Using a scope to enter the knee joint and “clean up” the cartilage
- Not supported by RCTs but commonly done
- 2 studies – 180 men under 75 – randomly assigned to arthroscopic washing, debridement or sham surgery
 - 24 months – no difference in outcomes
 - 178 men – moderate to severe osteoarthritis – randomly assigned arthroscopy + PT or medical treatment + PT
 - 24 months – no difference
- OA plus a torn meniscus
 - No difference compared to sham surgery
- Lesson – avoid arthroscopic surgery for arthritis of the knee

Knee pain

- 164 patients with chronic knee pain randomized to glucosamine-chondroitin or placebo
- by 6 months, patients treated with placebo experienced larger decreases in pain scores and function scores than patients treated with glucosamine plus chondroitin sulfate
- Stopped the study because there was one treatment (placebo) was so favorable
- Industry sponsored!

Coronary Stents for Stable CAD

- PCI (percutaneous coronary interventions) – stents and balloon angioplasty
- Provided an alternative to bypass grafts (and medicines)
- 2000 patients randomized to medical therapy or angioplasty with stent
 - No reduction in heart attacks, heart failure or death in 2 years
 - After 2 years, higher death rates in stents
- VA study - 12 year follow-up – medical therapy versus PCI
 - No difference in survival

MRI for Back Pain

- 2009 meta-analysis
 - No difference in pain in 6-12 months
 - No differences in disability
- Lots of findings in normal people
 - Disk herniations in 22%-67%
 - Spinal stenosis in 21% over 60
 - Arthritis (with no pain) in 60%-67%
- Lesson – only image if “red flags”



Back Pain Red Flags

- ❑ Low of bowel or bladder control
- ❑ Cancer that spreads to bone
- ❑ Fever
- ❑ Trauma
- ❑ Complete loss of muscle strength or sensation

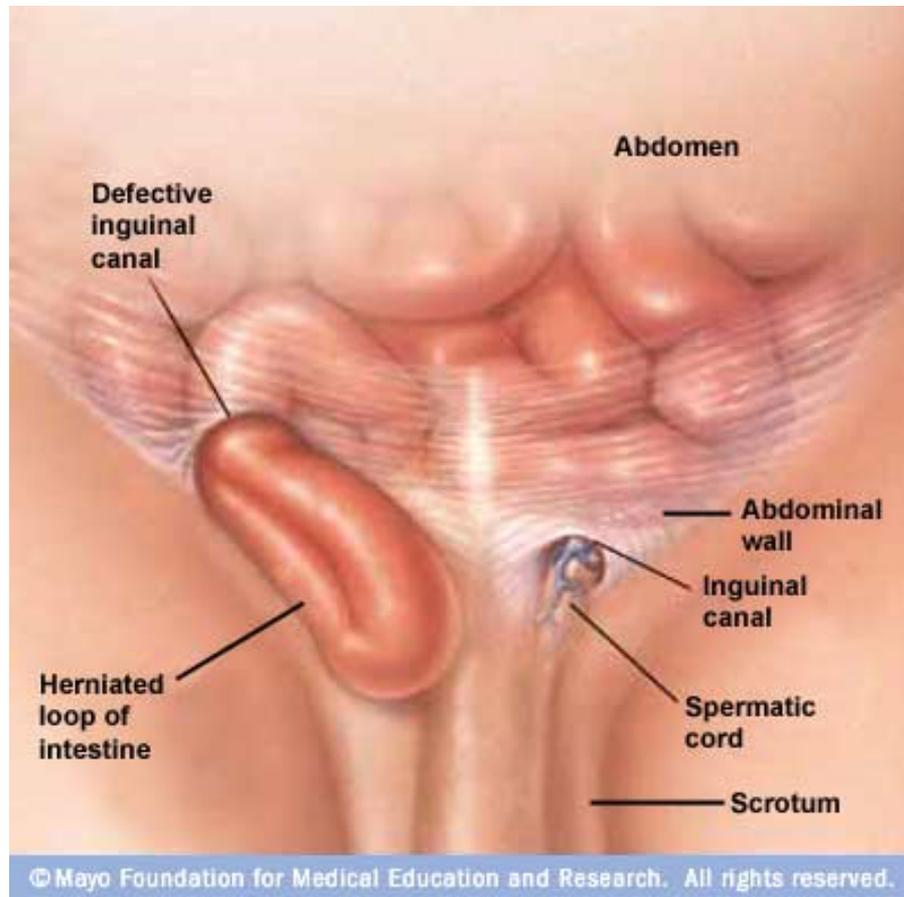
Placebos as Placebos

- 83 patients with 3-months back pain
 - 87% on pain meds
 - 40% adjuvant meds (gabapentin or relaxant)
 - 20% antidepressants
- Half of the patients were also given 2 placebo tablets twice a day. They were told that it was an inactive placebo, but:
 - it could still have a powerful effect;
 - the body can automatically respond to placebo;
 - a positive attitude is helpful but not necessary; and
 - the placebo must be taken faithfully.
- Knowingly taking placebo significantly decreased maximum reported pain, minimum reported pain, and usual pain as compared with usual therapy only

Tonsillectomy

- 40 years ago it was the most common surgery in children
 - Infection
- Now is only done for same indication in both children and adults
 - Obstructive sleep apnea

Inguinal Hernia Repair





Hernia Complications

- None
- Pain
- Incarceration
- Strangulation

Philosophy of “Risk”

- Watchful waiting versus preventive surgery
- 720 men (40-65) randomly assigned to waiting or surgery - followed 2 years
 - No differences in pain scores or complications
 - At 15 months, 15% of wait group had surgery
 - Only 2 patients required urgent surgery

PSA Testing

- Prostate cancer is a common cause of death
 - 161,000 new cases a year
 - 26,700 deaths a year
- Lifetime risk of cancer is 16%, but risk of death from it is 2.9%
- 85% of 80-year old men dying of other causes have prostate cancer on autopsy
- The USPSTF recommends *against* routine screening (Grade D)

Rationale

- A substantial percent of positives will have cancer that will not progress or will progress slowly
- Risk of “overdiagnosis” increases with screening and biopsy
 - US Trial – no survival benefit
 - European trial reduction in death in 1 person out of 1000 screened (only seen in 2 of 7 countries)
 - All-cause mortality not decreased



Harms of Overdiagnosis

- 80% of positives are false positive
- Psychological
- Risk of biopsy
- Harms of interventions
 - Incontinence
 - Erectile dysfunction

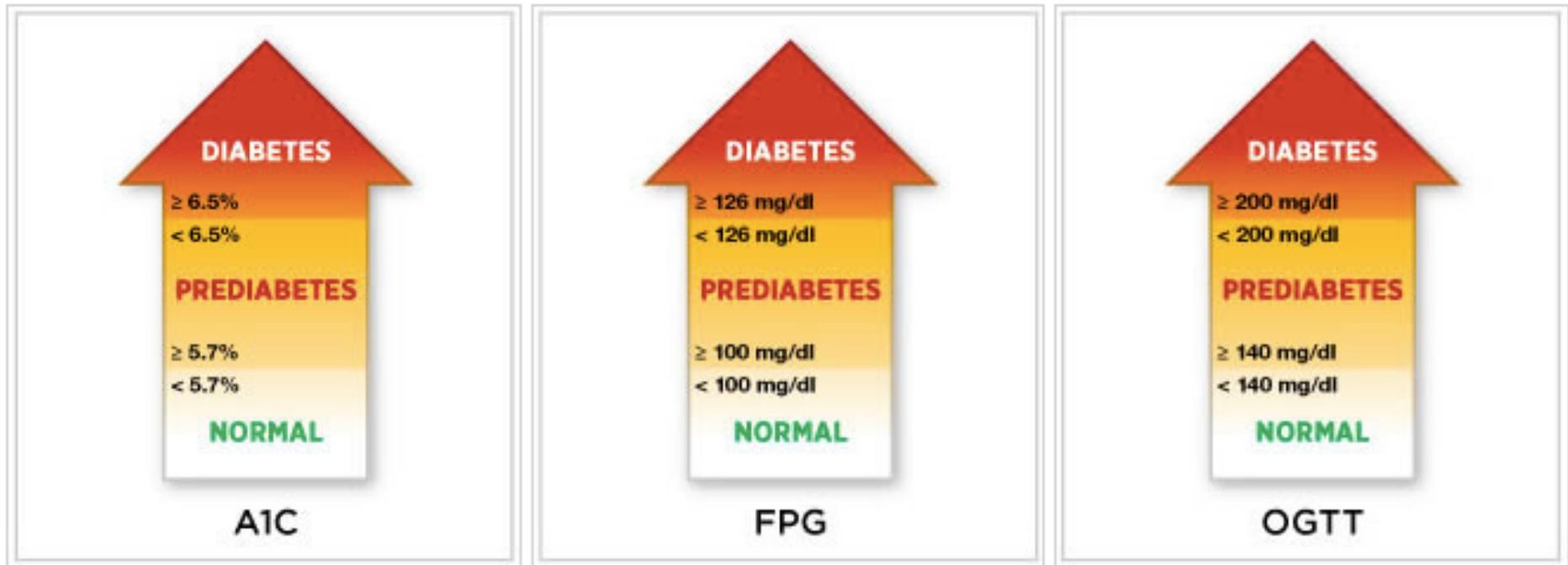
First placebo-controlled, randomized treatment trial for isolated calf DVT.

- 259 adults with first calf deep vein blood clot (DVT), diagnosed by ultrasound,
- Treated with blood thinner (heparin) or placebo for 6 weeks;
 - Patients with active cancer or previous venous thromboembolic disease were excluded.
 - About half of the patients had reversible risk factors (i.e., estrogen therapy or recent surgery, immobilization, or prolonged travel).
- Outcomes - extension of calf DVT, opposite leg DVT, or pulmonary embolism at 6 weeks) occurred in
 - 3% of nadroparin patients and 5% of placebo patients — a nonsignificant difference.
 - Major bleeding occurred in 4% of heparin patients and no placebo patients ($P=0.03$).
 - No participant died.

Future?

- PPI for dyspepsia
 - 113 million scrips/yr - 53% to 69% inappropriate
 - C. def toxin OR 1.52 H2 , 1.75 PPI (1.86 >80)
 - Fx – 1.25 -1.32 for spine and wrist
 - Increased risk of pneumonia
- Alternatives - tincture of time (many cases of heart burn resolve on their own), behavioral changes (eg, eating smaller meals [especially before bed], weight loss, smoking cessation, stress reduction), raising the head of the bed
- Aricept for dementia
- Meds for mild hypertension
- Abandon “pre-” labels

“Pre-diabetes”



A1C – hemoglobin A1C – an estimate of average blood sugar over 3 months

FPG – fasting plasma glucose

OGTT – oral glucose tolerance test – standard glucose drink – 2 hrs later test glucose

Accuracy of “Prediabetes” Tests

Test	Sensitivity	Specificity
A1C	0.49	0.79
FPG	0.25	0.94
OGTT	0.97	0.91

Sensitivity – the proportion with the disease who have a positive test

Specificity – the proportion without the disease who have a negative test

“Although there is a correlation between measures of glycemia and cardiovascular risk, their addition to conventional cardiovascular risk factors is not associated with a clinically meaningful improvement in prediction of CVD risk.” Up-to-Date, 2017

Harms of Labelling

- Psychological – anxiety, worry, depression, stress
- Increased exposure to the medical care system
 - Increased tests, increased false positives
- Expansion in indication of drug use
 - Adverse drug events, cost
- Little evidence of benefit
 - We already know what the treatment for increased CVD risk is



A Risk of a Risk

- Prediabetes is a risk factor for developing diabetes
- Diabetes is a risk factor for CVD
- 5% -10% of “prediabetes” progresses to diabetes
- Lifestyle modification lowers the conversion by over 50%
- US trial (DPP) showed lifestyle improved risk better than metformin treatment
- Some evidence that use of a medication decreases lifestyle modification

Lifestyle versus Medication

Intervention	Incidence (new cases)	Reduction
Lifestyle	4.8	58%
Metformin	7.8	31%
Placebo	11.0	(comparison)

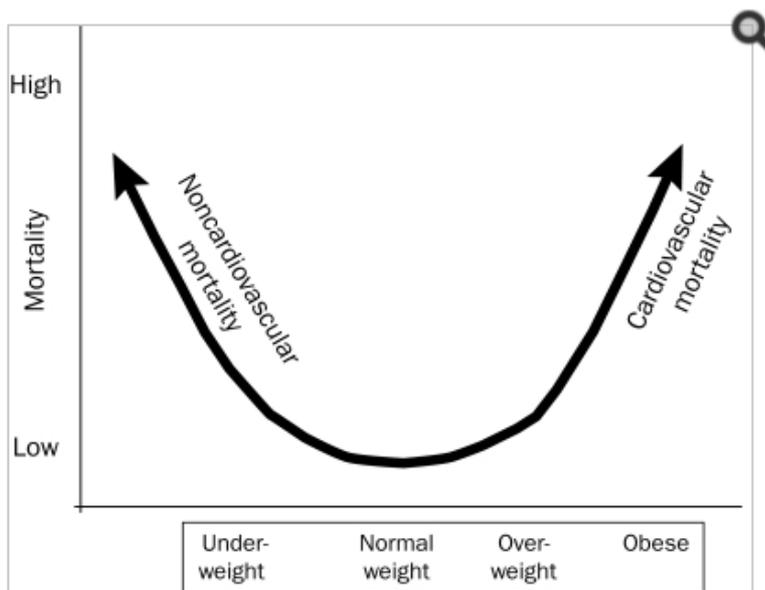
Almost 3 year follow-up

Metformin side effects – stomach (10% - 53%), nervous system (1%-5%), weakness (10%)

J (or U) Shaped Curves

PMC full text: [Mayo Clin Proc. 2010 Feb; 85\(2\): 112-114.](#)
doi: [10.4065/mcp.2009.0777](#)
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FIGURE.



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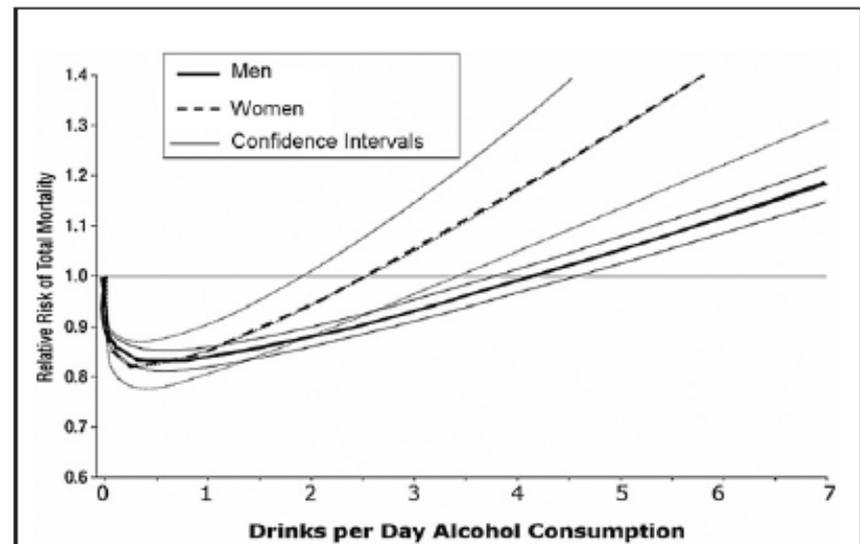
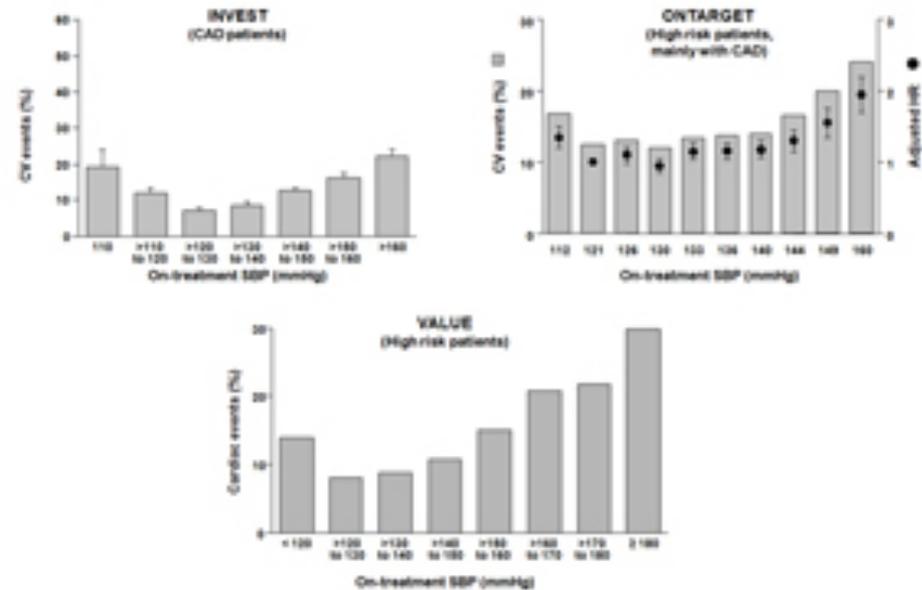
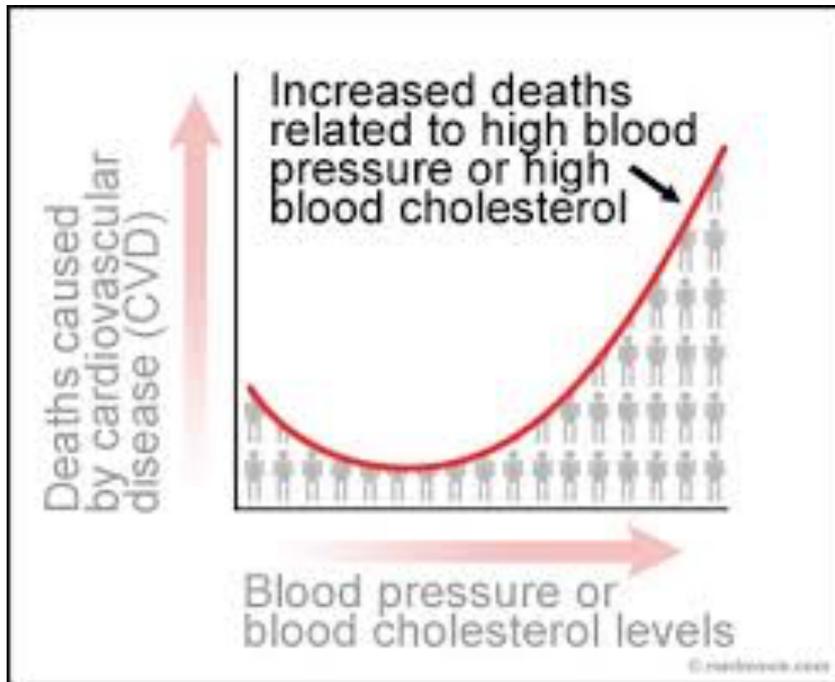


Figure 1 Alcohol and All-Cause Mortality

The relationship of daily alcohol consumption to the relative risk of all-cause mortality in men and women. Reproduced with permission from DiCastelnuovo et al. (2).

J (or U) Shaped Curves



Chocolate for CVD

- Six systematic reviews – observational studies - 75,408 to 157,809 adults
 - CVD – RR 0.63
 - Heart attack – 0.90
 - Stroke – 0.95
 - Heart failure – 0.81
 - Death – not reported
- Possible bias
 - Non-randomized, generally younger, low BMI, active
- Risk factor modification (systematic review, 10-20 RCTs)
 - Reduced BP 2.8-4.5 mm HG
 - Reduced LDL 8 mg/dl